

VertiFlex®

Superion® InterSpinous Spacer



Caution: Federal Law restricts this device to sale by or on the order of a physician.

This brochure will provide you with information about the Superion® InterSpinous Spacer, a new treatment for lumbar spinal stenosis.

Your doctor will answer any questions you have regarding lumbar spinal stenosis and the Superion® as a treatment for you.

Vertiflex®
1351 Calle Avanzado, Suite 100
San Clemente, CA 92673
(949) 940-1400

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INTRODUCTION

After reviewing your medical history, x-rays, and other tests, your doctor has decided that you need surgery for the relief of back or leg pain. This brochure can help you make a better choice on how to treat your pain.

WHAT IS THE SUPERION®?

The Superion® device is a titanium alloy implant that fits between the spinous processes of the bones in your lower back (please see Figure 2 below). The Superion® device can help relieve your back pain symptoms by stabilizing the movement of your spine. This may help reduce the pain in your back, groin or legs. Titanium alloy is often used in bone repair in the body.



Figure 1: The Superion® InterSpinous Spacer. The implant fits between the spinous processes and the wings are designed to prevent the implant from moving

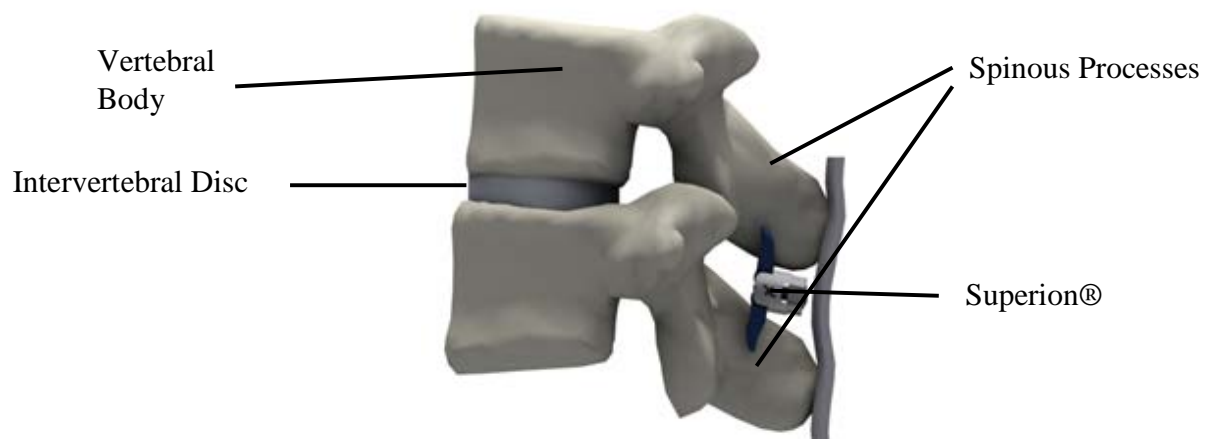


Figure 2: Superion® implanted in the spine

WHAT IS SPINAL STENOSIS?

Spinal stenosis is a narrowing of the spinal canal. Thickening of tissue that connects two bones (ligaments), bulging of discs, or overgrowth of bone can cause it. The spinal cord and nerve fibers that exit the spinal canal (nerve roots) can become crowded and pinched. This may lead to pain, numbness, tingling, and/or weakness in the back and legs. This pain is especially noted when you walk.

WHAT ARE MY TREATMENT OPTIONS?

There are ways to treat spinal stenosis. Some are:

- Non-surgical ways
 - Your doctor can inject you with a drug (steroids) to lower swelling and treat pain in your hips or down the leg. Pain relief from this may not last long. You should not have more than three injections in a six month time.
 - You can rest.
 - You can take physical therapy and exercise.
- Surgical ways
 - Decompression surgery only. This surgery removes the bone around your nerves causing the pain. This surgery helps relieve pressure on your spinal nerves.
 - Implantation of an interspinous device like Superion® or X-STOP® with no surgical decompression.
 - Direct decompression and spinal fusion. In spinal fusion, your doctor puts some of your bone (bone graft) between two bones in the area of the decompression surgery. Your doctor uses screws and rods to hold the bones in place. The bone graft is usually either spinal bone removed during the decompression surgery or bone from your hip removed through a separate cut. The purpose of the bone graft is to grow bone between the two bones. This is supposed to stop motion in that portion of the spine. The rods and screws are usually left in your spine unless a problem happens. If this happens, the device is removed or replaced.

Discuss your alternatives with your physician and select the treatment method that best seems to meet your current pain level and lifestyle.

ARE YOU A CANDIDATE FOR THE SUPERION® PROCEDURE?

To be a candidate for treatment with the Superion®:

- You must be skeletally mature.
- You must have pain, numbness, and/or cramping in the legs related to spinal stenosis in your lower back. One sign of having spinal stenosis is it is hard to walk a long way, such

as ½ mile. Another sign is having pain in your lower back while standing that goes away when you bend forward.

- You must have been treated by a doctor for at least 6 months with “non-surgical treatments” like those described on page 4.

WHO SHOULD NOT RECEIVE THE SUPERION®? (CONTRAINDICATIONS)

Do not choose Superion® if any of these is true:

- You have spinal anatomy or instability that would not allow use of Superion®. Examples of this are scoliosis or fracture of the spinous process. The Superion® may not function properly and you may need additional surgery to relieve your pain. Tell your doctor if you have ever had a problem with your back.
- You have bone fractures or reduced bone density (osteoporosis). These conditions may lead to more bone fractures in your back. Tell your doctor if you have ever had a broken bone or have problems with bone density.
- You have any infection. Tell your doctor if you have any infection. Patients with infections are at risk for a deep infection if they have Superion® implanted. They would need another surgery to remove it.
- You are allergic to titanium or titanium alloy. Patients who are allergic might have to have more surgery to remove the Superion®. Tell your doctor if you think you ever had a reaction to a metal or an implant. You may not know if you are allergic to the Superion® device.
- You have cauda equina syndrome. This is a severe spinal nerve compression that causes loss of bowel or bladder function, loss of sensation in the buttocks and groin, and weakness in the legs. Tell your doctor if you have ever had a problem with going to the bathroom due to your back pain or weakness in your legs. Patients with cauda equina syndrome would not benefit from the Superion® device.

WHAT WARNINGS SHOULD I KNOW ABOUT WHEN SUPERION® IS USED?

Do not do any strenuous physical activity for 6 weeks after your surgery. Examples of strenuous physical include lifting more than 10 pounds. Don’t do sports until your doctor tells you that you can. Sports include swimming, golf, tennis, racquetball, running, and jogging. Your Superion® device may move or break part of your spine if you are too active too soon after surgery. This could cause pain. You could need more surgery. Each patient is different. Ask your doctor what it is OK to do after surgery.

Tell your doctor after surgery if you have fluid leaking from your wound, redness around your wound, or separated edges at the site of the wound. These problems can lead to serious infection

and require more surgery if your doctor does not treat them. You may need to ask another person to look at your wound to see if it is leaking.

Tell your doctor as soon as possible after your surgery if you have pain or swelling in your back or if you feel numbness in your legs or buttocks. These symptoms can be a sign that the Superion® device is not working properly. You may need more surgery.

If you fall, tell your doctor. A fall may hurt you seriously.

WHAT ARE PRECAUTIONS FOR THE USE OF SUPERION®?

Follow all of your doctor's instructions after your surgery. This will help you recover better. Each patient is different. Your doctor will know what's best for you. If you don't do what your doctor says after surgery it may delay your recovery and cause you more pain.

If a doctor sends you to have an MRI exam, tell him or her you have a Superion® device. This is important because there are special instructions for use of an MRI on someone with a Superion® device.

WHAT PROBLEMS MAY HAPPEN FROM SUPERION® SURGERY? (RISKS)

- Less back movement than before surgery due to:
 - Stiff ligaments (spinal ligament ossification).
 - An overgrowth of bone (heterotopic ossification) at the spinal level.
 - Vertebrae fusing together.
- The implant breaking, moving, or wearing.
- Needing additional back surgery.
- Fracture in the spinous process at the surgery level.
- The development of a recurrent spinal problem at the surgery level, as well as the development of a new spinal problem above or below the treated spinal level.

There is also the risk that the surgery may not be effective in relieving your symptoms or may cause worsening of your symptoms. If this occurs, you may need another surgery in order to help you feel better. 23 out of every 100 patients who had the Superion® device had the device removed or other procedures to try to stop their pain.

WHY MAY SUPERION® WORK? (BENEFITS)

The Superion® implant is designed to keep your spine still so when you stand upright the nerves in your back will not be pinched or cause pain. In addition, the Superion® implant is intended to allow you to continue to move your back more than with a fusion surgery. With the Superion® implant in place, you should not need to bend forward to relieve your pain.

We studied the Superior® implant in a clinical trial to compare it to the X-STOP® device. In our study of 392 patients, 191 patients had the Superior® implant and 201 patients had the X-STOP® implant. 51 out of every 100 patients who had the Superior® device had a successful outcome after two years. A successful outcome meant they had relief from their pain and did not require additional surgery. A similar outcome (48 out of 100 patients) was experienced with patients who had the X-STOP® device. We did not compare the Superior® device with any non-surgical method of treatment. We did not look at the benefit beyond two years after surgery.

WHAT CAN I EXPECT BEFORE SUPERION® SURGERY?

You and your doctor may choose for you to have surgery with Superior® Interspinous Spacer. If so, there are several things you can do to help you have the best possible results for your surgery. Your doctor will give you specific instructions prior to your surgery that you should follow. You can also raise your chances of a successful outcome by eating well-balanced nutritional meals before your surgery. Poor nutrition can reduce the body's ability to heal.

WHAT CAN I EXPECT DURING SUPERION® SURGERY?

The procedure may be done in the operating room at the hospital. The Superior® implant is inserted through a small cut in the skin of your back. You will be given drugs so that you will be asleep during surgery. You will be unable to feel the surgery.

You will be placed on your stomach during the surgery. This will allow your doctor to bend your spine when the Superior® is inserted. The surgery to implant the Superior® typically lasts about one to two hours.

As part of the Superior® surgery, your doctor will first separate the supraspinous ligament to access the surgical area of the spine. The space between the bones in your back will be measured to pick out a device size.

Next, the Superior® is placed between two spinous processes in the back of your spine in the closed position. After insertion, the wings of the device are opened and locked in the final position.

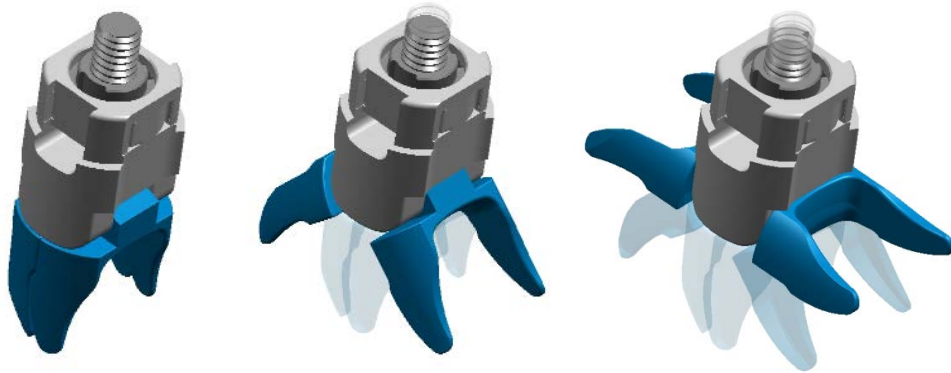


Figure 4: Superion® Implant in Closed and Extended Positions

WHAT CAN I EXPECT AFTER SUPERION® SURGERY?

Based on the clinical results, 81 out of every 100 Superion® patients had significant pain relief at two years. Your outcome at two years, if you are treated with Superion®, is expected to be no worse than if you were treated with X-STOP®. In addition, Superion® subjects lost a lot less blood during the implant surgery than X-STOP® subjects.

Once the doctor says you can leave the hospital, you may need physical therapy. Your doctor may ask you to return for an examination about six weeks later. Your doctor may also ask you to reduce your physical activities in the first 6 weeks after your operation. In the clinical study, patients were allowed to travel and engage in light activity such as walking as soon as they felt they could. It is important for you to realize that you have had a surgical operation. You should not participate in some activities until your doctor has said you may do so. Please ask your doctor when you can start doing certain activities. Your results may be different from patients in the clinical study.

After your surgery, medication will be provided to you by your doctor. During the clinical study, walking during the first 6 weeks following surgery was usually acceptable. Please listen to your doctor's instructions on how much activity you can do and for how long after surgery.

WHEN SHOULD I CALL MY DOCTOR?

If you continue to have pain in your back or legs, please see your doctor immediately. If you feel like the Superion® is not working, please see your doctor immediately. If your doctor thinks the Superion® needs to be removed or replaced, a new surgery will be needed.

WHERE CAN I FIND OUT MORE INFORMATION?

If you have any questions about Superior®, you may ask your doctor. For additional information, you may call Vertiflex's information hotline at XXX-XXX-XXXX. You may also find additional information at www.vertiflexspine.com.

WILL MY IMPLANT SET OFF A METAL DETECTOR?

The metal in Superior® may affect MRI and metal detectors. You will be given a patient ID card by your surgeon. This card lets people know you have a Superior® implant inside you. You should show this card when you have x-rays and MRIs. When you pass through an electronic detection system, you may use this card to tell security that you have this device in your spine.

WHAT HAVE CLINICAL STUDIES SHOWN ABOUT SUPERION®?

The clinical study results show the Superior® is reasonably safe and effective for the treatment of spinal stenosis. The Superior® was tested in a carefully controlled research study. This study took place in thirty one hospitals across the United States. A total of 392 patients were in this study. 191 patients received a Superior® device, and 201 patients received an X-STOP® device. Patients in this study had lumbar spinal stenosis, similar to you. These patients were treated by their doctors for at least 6 months to relieve their pain without surgery before entering the study. Patients were randomly assigned to their treatment and did not know before surgery what treatment they would get.

Please talk with your doctor for more details about the clinical study and its results.

MORE ABOUT YOUR CONDITION

Your spine is very important. It supports the structure of your body and protects your spinal cord, which relays information to and from your brain. It is also responsible for the most basic movements of your body, such as nodding your head, sitting, standing, and walking.

Your spine consists of a column of 24 bones called vertebrae. These vertebrae extend from your skull down to your hip bones (Fig. 5). Between the vertebrae are discs of soft tissue. The vertebrae join together like links in a chain. These provide support for your head and body while the discs act as stabilizing cushions, or "shock absorbers." In addition to providing support, the spine surrounds and protects a cylinder of nerve tissues called the spinal cord. The spinal cord is surrounded by a part of the vertebrae creating a channel called the spinal canal.

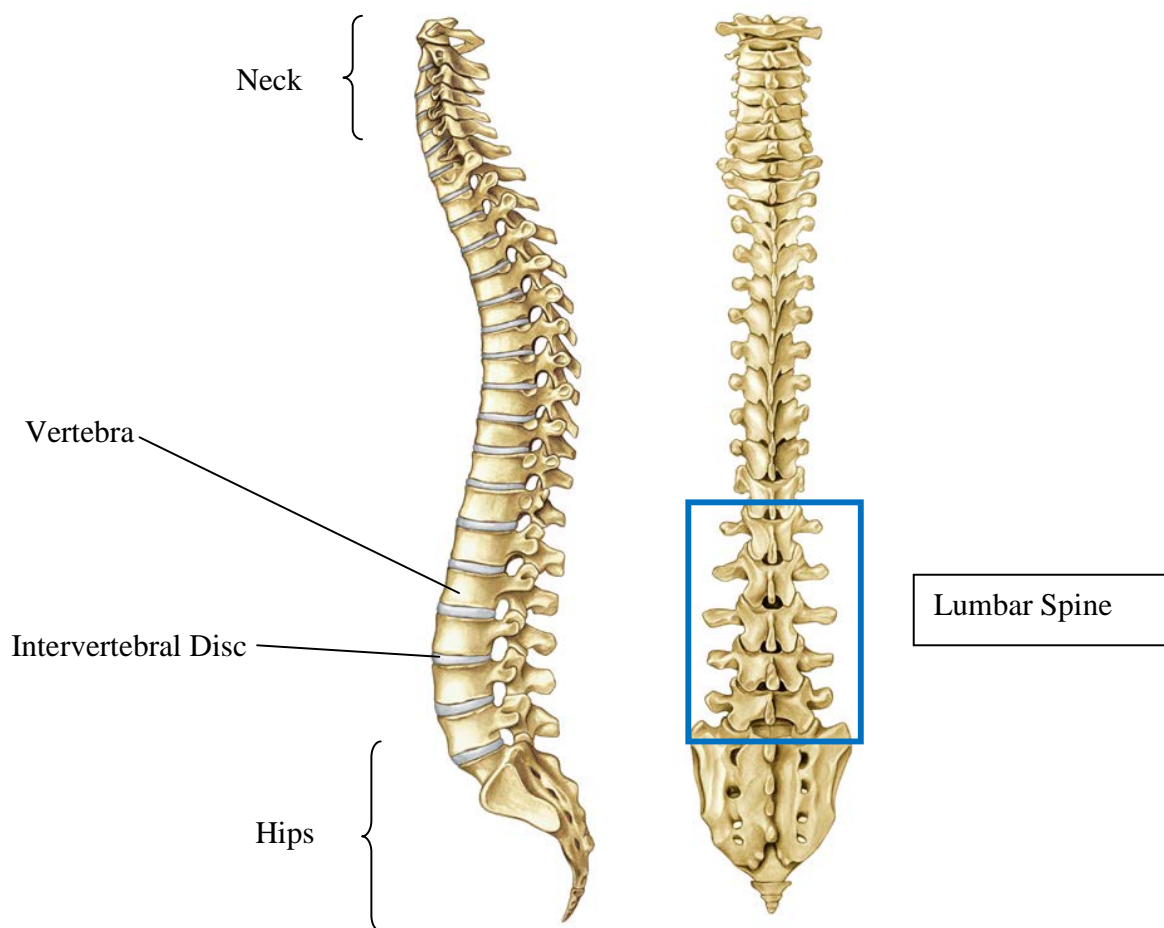


Figure 3: The Spine

Normally there is space between the spinal cord and the borders of the spinal canal. In this case, the nerves are free and are not pinched (Fig. 6).

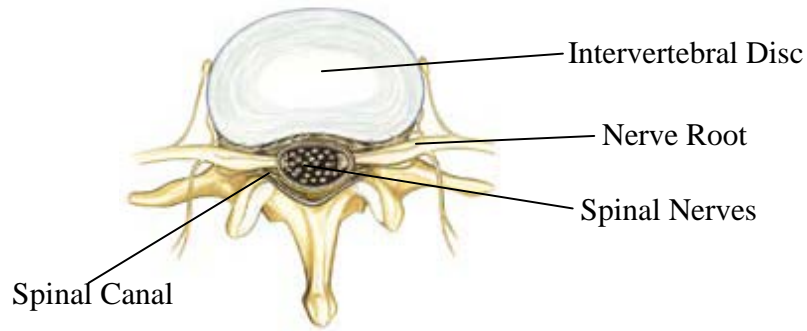


Figure 4: Healthy Spinal Column



Figure 5: Healthy Spine

What is Spinal Stenosis?

Spinal stenosis is defined as a narrowing of the spinal canal. This narrowing can occur from thickening of ligaments (tissue that connects two bones), bulging of discs, or overgrowth of bone. The spinal cord and nerve fibers that exit the spinal canal (nerve roots) can become crowded and pinched. This may lead to pain, numbness, tingling, and/or weakness in the back and legs. This pain is especially noted while walking (Fig. 8).

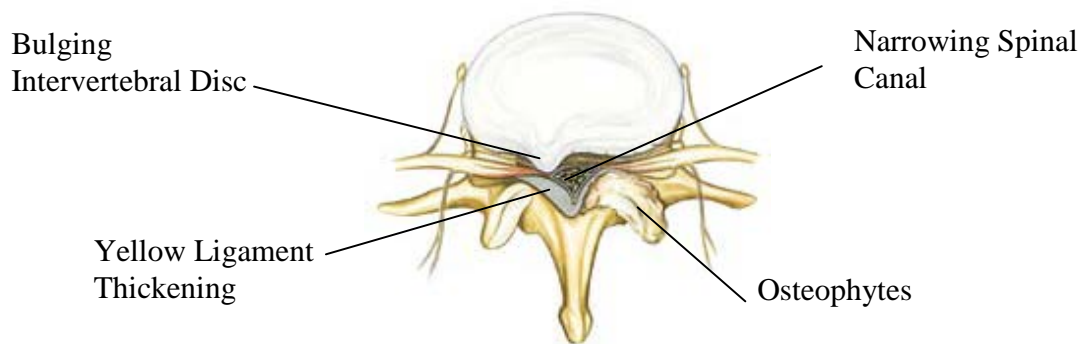


Figure 6: Spinal Column with Stenosis

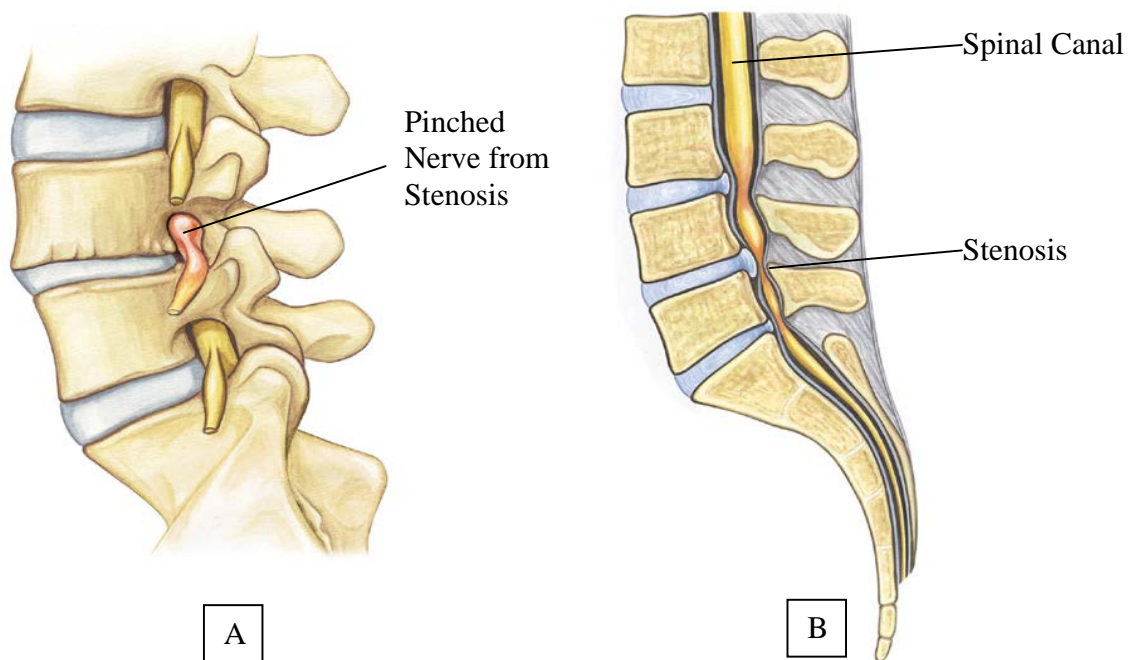


Figure 7: Stenotic Spine
A: Lateral Spinal Stenosis
B: Central Spinal Stenosis

Spinal stenosis is the gradual result of aging and “wear and tear” on the spine from everyday activities. This wear and tear on the spine can lead to pressure on the nerves that may cause pain and/or damage.

HOW DO I KNOW IF I HAVE SPINAL STENOSIS?

If you suffer from lumbar spinal stenosis you may feel various symptoms. These symptoms include:

- You may feel a dull or aching back pain spreading to your legs.
- You may feel a numbness and "pins and needles" in your legs, calves or buttocks.
- You may feel a weakness, or a loss of balance.
- You may feel a decreased endurance for physical activities.

Before saying you have stenosis, it is important for your doctor to rule out other conditions that may produce similar symptoms. Your doctor will ask you to describe any symptoms you have and how these symptoms have changed over time. Your doctor will ask you the treatments you have had for these symptoms. This includes medications. Additional radiology tests will be needed to confirm that you have spinal stenosis.

SUMMARY

This brochure has been designed to help you understand the Superior® Interspinous Spacer as an option to treat your spinal stenosis. It also should give you the information you need to be an active participant in your own care.

We hope that you take the time to discuss all possible treatments with your doctor. You should also learn as much as you can about your own pain and what is causing it.

We also want to make sure that you understand all of the risks of surgery and the potential complications after surgery.

It is important that you understand exactly the procedure for the Superior® surgery before you decide to move forward. This includes the risks, benefits and other treatments. Always remember that the final decision to have surgery is up to you.